UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff, v. 169 / 50kg drums, more or less, of an article of drug for human use, labeled in part: (drum) ** PVP IODINE (USP) *** POVIDONE IODINE (USP) *** FOR MANUFACTURING PROCESSING OR REPACKING *** NET WT.: 50.00 KG *** and all other articles of drug, including finished and in-process products, and drug components, including active and inactive ingredients, of any lot number, size, or type of container, whether labeled or unlabeled, that are determined to consist in whole or in part of components that have originated from outside the State of Wisconsin, which articles were manufactured by, or are used in the manufacture of finished dosage form drugs by, H & P Industries, Inc., and that are located anywhere on the premises of H & P Industries, Inc., 700 W. North Shore Drive, Hartland, Wisconsin,	)	Case No. 11-C-0319 **CONSENT DECREE OF CONDEMNATION, FORFEITURE, AND PERMANENT INJUNCTION**

Defendants-*in-rem*,	)
	)
and	)
	)
H & P INDUSTRIES, INC.,	)
TRIAD GROUP, INC.,	)
TRIAD DISPOSABLES, INC., corporations	)
	)
and	)
	)
ERIC C. HAERTLE, DAVID R. HAERTLE,	)
and DONNA L. PETROFF, individuals	)
	)
Defendants.	)

On March 31, 2011, Plaintiff, the United States of America, by and through its attorneys, filed a verified Complaint for Civil Forfeiture *In Rem* (the "Complaint") against the articles described in the above caption located at 700 West North Shore Drive, Hartland Wisconsin.

The articles proceeded against are articles of drug within the meaning of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 321(g)(1). The Complaint alleges, among other things, that the above-captioned articles are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with the current Good Manufacturing Practice ("CGMP") regulations, 21 C.F.R. Parts 210-11 ("CGMP" as defined in this Decree can refer to the CGMP statutory and regulatory provisions for both drugs, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-11, and/or devices, 21 U.S.C. §§ 351(h) and 21 C.F.R. Part 820, as indicated herein). Pursuant to a Warrant for Arrest *in rem* issued by this Court, the United States Marshal for this

district executed the seizure on April 4-5, 2011.

On April 14, 2011, H & P Industries, Inc., and on April 19, 2011, Triad Group, Inc. (collectively referred to hereafter as "Claimants"), each intervened and filed a statement of interest for the seized articles. Claimants, along with Triad Disposables, Inc., and Eric C. Haertle, David R. Haertle, and Donna L. Petroff, individuals (hereafter, collectively, "Defendants"), having appeared and voluntarily consented to the entry of this Decree without contest, without admitting or denying the allegations in the Complaint, before any testimony has been taken, and waiving the filing and service of an amended complaint seeking injunctive relief, and the United States having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED, as follows:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district under 28 U.S.C. §§ 1391(b)-(c) and 1395.

2. Claimants affirm that they are the sole owners of the seized articles, and that no other person has an interest in the articles. Claimants further affirm that they shall indemnify and hold the United States harmless should any party or parties hereafter file or seek to file a statement of interest or to intervene in this action, or seek to defend or obtain any part of the seized articles.

SEIZURE PROVISIONS

3. As alleged in the complaint, the seized articles are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not

operated and administered in conformity with CGMP. See 21 C.F.R. Parts 210-11.

4. The seized articles are therefore condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Pursuant to 21 U.S.C. § 334(e), Claimants shall pay to the United States all court costs and fees, storage and other proper expenses to date, and such additional expenses as may hereinafter be incurred and taxed. Claimants shall pay these costs in full within ten (10) calendar days of receiving written notice from FDA of such costs.

6. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) calendar days of entry of this Decree, Claimants shall execute and file with the clerk of this Court a good and sufficient penal bond with surety in the amount of four million dollars ($4,000,000) in a form acceptable to the clerk of this Court and payable to the United States of America, and conditioned upon Claimants abiding by and performing all of the terms and conditions of this Decree and of such further orders and Decrees as may be entered in this proceeding.

7. After paying the costs pursuant to paragraph 5 and filing the penal bond with the clerk of this Court pursuant to paragraph 6, Claimants shall give written notice to FDA that Claimants, at their own expense, are prepared to attempt to bring the condemned articles into compliance with the law under the supervision of a duly authorized FDA representative.

8. Claimants shall not commence, permit any other person to commence, or cause any other person to commence attempting to bring the condemned articles into compliance with the law unless and until Claimants (a) submit a written statement to FDA detailing Claimants' proposed plan to bring the condemned articles into compliance under FDA's supervision ("reconditioning proposal"); and (b) Claimants receive FDA's written approval of the reconditioning proposal and to commence attempting to bring the condemned articles into

compliance with the law. Claimants' reconditioning proposal shall specifically identify which reconditioning measures apply to which condemned articles. FDA's decision regarding the adequacy of the reconditioning proposal shall be final. If the reconditioning proposal is acceptable with regard to some of the condemned articles and not others, FDA shall specify those condemned articles for which the reconditioning proposal is acceptable and unacceptable. Claimants shall then submit, within ten (10) calendar days of receipt of FDA's letter, either a revised reconditioning proposal for those articles for which the initial plan was unacceptable or a plan to destroy those articles as set forth below. FDA shall respond in writing to Claimants' revised reconditioning proposal to notify Claimants as to whether the revised proposal is acceptable. If Claimants have not submitted a revised reconditioning proposal within twenty (20) calendar days of receipt of FDA's letter, or if FDA finds that the revised reconditioning proposal is unacceptable, Claimants shall cause that portion of the condemned articles for which no revised reconditioning proposal was submitted or for which the revised reconditioning proposal was deemed unacceptable, to be promptly destroyed at Claimants' expense and under the supervision of an FDA representative under the terms of paragraph 15.

9. Following Claimant’s payment of costs and posting of the Bond, as required by paragraphs 5-6 of this Decree, and following Claimant’s receipt of written authorization to commence reconditioning as described in paragraph 8, the United States Marshal, upon receiving notice from the United States Attorney or FDA, shall release the appropriate Lot of condemned articles, as described in paragraphs 9 (A) – (C) below, from his custody to the custody of Claimant’s for the sole purpose of attempting to bring such articles into compliance with the law in accordance with the reconditioning proposal. The schedule for release of the condemned articles is as follows:

A. The condemned articles in Lot 1, consisting of approximately one-third (1/3) of the articles (by value), as identified by Claimant and subject to FDA concurrence, shall be released to Claimants for the sole purpose of attempting to bring Lot 1 into compliance with the law.

B. If and only if Defendants comply with all the terms of this Decree with respect to Lot 1, to FDA's satisfaction as confirmed by FDA in writing, the condemned articles in Lot 2, consisting of approximately one-third (1/3) of the articles (by value), as identified by Claimant and subject to FDA concurrence, shall be released to Claimants for the sole purpose of attempting to bring Lot 2 into compliance with the law.

C. If and only if Defendants comply with all the terms of this Decree with respect to Lot 2, to FDA's satisfaction as confirmed by FDA in writing, the condemned articles in Lot 3, consisting of approximately one-third (1/3) of the articles (by value), as identified by Claimant and subject to FDA concurrence, shall be released to Claimants for the sole purpose of attempting to bring Lot 3 into compliance with the law.

In no event shall a Lot be released to Claimants for the purpose of attempting to bring the condemned articles into compliance pursuant to this Decree unless there is on file with the Clerk of the Court a penal bond in the amount of four million dollars ($4,000,000).

10. Claimants shall at all times, until the condemned articles have been released in writing by an FDA representative, retain those articles intact for examination or inspection by the FDA representative in a place made known to and approved by FDA, and shall maintain the records or other proof necessary to establish the identity of the articles to the satisfaction of the FDA representative.

11. Within forty-five (45) calendar days of receiving written authorization to commence attempting to bring the condemned articles into compliance with the law, Claimants shall complete their attempt in accordance with the reconditioning proposal approved pursuant to paragraph 8, and under the supervision of FDA. Claimants shall destroy any article that has not been brought into compliance within ninety (90) calendar days of receiving written authority to commence implementing the reconditioning proposal, at their own expense and under the supervision of FDA, and shall file a notice with the Court certifying that such articles have been destroyed.

12. Claimants shall at no time, and under no circumstances whatsoever, directly or indirectly, cause or permit the shipment, sale, offer for sale, or other disposal of the condemned articles until:

A. FDA has had free access to the condemned articles in order to take any samples of the condemned articles or reconditioned goods or make any tests or examinations that are deemed necessary; and

B. FDA has released, in writing, the condemned articles for shipment, sale, or other disposition.

13. Claimants shall not sell, ship, destroy, or dispose of, or permit or cause another person to sell, ship, destroy, or dispose of, the condemned articles or any part of them in any manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act), in which they are disposed of or sold.

14. If Claimants breach any condition of this Decree, or any subsequent Decree or order in this proceeding, Claimants shall immediately return any of the condemned articles that have been released by FDA pursuant to paragraph 8 to the United States Marshal for this district,

or otherwise dispose of them at their own expense pursuant to an order of this Court. In the event that return of any of the condemned articles becomes necessary pursuant to this paragraph, Claimants shall be responsible for all costs of storage and disposition that are incurred by the United States.

15. If, within ninety (90) calendar days of the entry of this Decree, Claimants do not submit a reconditioning proposal as described in paragraph 8 above, Claimants, at their own expense and under the supervision of FDA, shall destroy such articles and make due return to this Court regarding their disposition. Claimants shall reimburse the United States for any costs incurred pursuant to this paragraph, and shall pay such costs within twenty (20) calendar days of receiving an invoice from FDA. Destruction under this Decree shall be in a manner that complies with all federal, state, and local environmental laws, including, but not limited to, the requirements of the National Environmental Policy Act of 1969.

16. If Claimants fail to abide by and perform all the terms and conditions of paragraphs 5-15 above or any such further order or Decree as may be entered in this proceeding relating to attempts to bring the condemned articles into compliance with the law, then the bond described in paragraph 6 above shall, on motion of the United States in this proceeding, be forfeited in its entirety or in such part as FDA, in its discretion, determines is appropriate to the United States of America and judgment entered thereon, and any condemned articles remaining in the custody of the United States Marshal shall be forfeited and disposed of pursuant to further order of this Court.

17. The United States Attorney for this District, upon being advised by an FDA representative that all of the condemned articles have been brought into compliance with the Act and the requirements of this Decree, or destroyed in compliance with this Decree, and that

Claimants have paid all costs submitted to Claimants as of the date of FDA's notice to the United States Attorney, will transmit such information to the clerk of this Court, whereupon the bond given in this proceeding shall be discharged.

INJUNCTIVE LANGUAGE

18. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, individuals, directors, corporations, subsidiaries, affiliates, partnerships, and "doing business as" entities) who receive actual notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) and/or any device that is adulterated within the meaning of 21 U.S.C. § 351(h); and

B. Causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B) and/or any device within the meaning of 21 U.S.C. § 351(h), while such drug or device is held for sale after shipment of one or more of its components in interstate commerce.

19. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, individuals, directors, corporations, subsidiaries, affiliates, partnerships, and "doing business as" entities) who receive actual notice of the Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly, manufacturing, processing, packing, labeling, holding, or distributing

any articles of drug, as defined by 21 U.S.C. § 321(g)(1), or any device, as defined by 21 U.S.C. § 321(h), at Defendants' facilities located at 700 West North Shore Drive, Hartland, Wisconsin (as well as any other location or any new location at which Defendants manufacture, process, pack, label, hold, or distribute drugs or devices), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with CGMP for drugs, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-11; and:

(1) Defendants establish and document management control over Quality Assurance ("QA") and Quality Control ("QC") for all of its facilities to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for management control over QA and QC shall be vested in an individual who shall be authorized and responsible for all QA and QC functions at all of Defendants' facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA and QC program ("QA/QC program") to ensure that all drug products manufactured, processed, packed, held, and distributed by Defendants at all of Defendants' facilities have the safety, identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the provisions of this Decree;

(2) Defendants have processes in place to ensure that when one or more drug manufacturing, processing, labeling, holding or distribution functions are contracted to another party, responsibilities are defined for each party involved, periodic audits are performed, the contracted site is adequately monitored, the parties supplying materials have been qualified, and product and process information is promptly transferred from Defendants to the contracted party;

(3) Defendants establish and follow scientifically sound written procedures for the

production and process control designed to assure that the drug products have the identity, strength, quality, and purity they are represented to possess;

(4) Defendants establish and follow scientifically sound written procedures for the in-process controls and tests, or examinations of uniformity of drug products;

(5) Defendants establish and follow a stability testing program to determine expiration dates;

(6) Defendants demonstrate that the equipment used in the manufacturing, processing, packing, and holding of drug products is of an appropriate design to facilitate operations for its intended use and is appropriately maintained;

(7) Defendants establish scientifically sound procedures to thoroughly investigate any unexplained discrepancies and failures of batches to meet any of their specifications and to extend the investigation to other batches that may have been associated with the specific failure or discrepancy;

(8) Defendants establish a Quality Control Unit with the responsibility for approving or rejecting all procedures or specifications impacting the identity, strength, quality, and purity of the drug product;

(9) Defendants implement a quality system that promptly identifies inconsistencies and adverse trends to ensure that emerging product quality issues are detected and corrective and preventive actions are implemented before the product is distributed;

(10) Defendants establish and follow scientifically sound development and manufacturing process design procedures to control all significant variables (including material attributes and processing parameters) affecting in-process material and final drug product specifications and quality attributes;

(11) Defendants establish appropriate facility and design equipment for adequate control over air pressure, microorganisms, dust, humidity, and temperature in drug products needed to manufacture their drug products;

(12) Defendants establish and conduct appropriate laboratory testing of each component and batch of drug product required to be free of objectionable organisms; and

(13) Defendants qualify their water system and develop and implement appropriate specifications and test plans to ensure that such water is of the quality needed to manufacture their drug products.

B. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in conformity with the applicable statutes and regulations including, but not limited to, 21 U.S.C. §§ 351(h) and 352(t)(2), and the Quality System and Medical Device Reporting regulations, in 21 C.F.R. Parts 820 and 803, and:

(1) Defendants adequately validate processes whose results cannot be fully verified by subsequent inspection and testing and establish and implement written procedures for monitoring and controlling process parameters for validated processes to ensure that specified requirements continue to be met, including validation of the sterilization process for any sterile lubricating jelly products and any other devices;

(2) Defendants establish and maintain written quality requirements that must be met by contractors, suppliers, and consultants, and adequate written procedures to ensure that all purchased or otherwise received components and services conform to specified requirements;

(3) Defendants establish and maintain written procedures for corrective and preventive actions and for documenting those activities;

(4) Defendants establish and implement written procedures to control the disposition of product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of non-conforming product;

(5) Defendants maintain accurate and complete complaint files and establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints and implementing effective corrections when errors or discrepancies are found;

(6) Defendants establish and implement written procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality;

(7) Defendants establish and implement adequate written procedures to control environmental conditions that could reasonably be expected to have an adverse effect on product quality;

(8) Defendants establish and implement adequate written procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria;

(9) Defendants establish and implement adequate written procedures for receiving device acceptance to ensure that incoming product is inspected, tested, or otherwise verified as conforming to specified requirements; and

(10) Defendants develop and implement adequate written medical device reporting ("MDR") procedures in compliance with 21 C.F.R. Part 803, and ensure that employees are trained on and understand the MDR requirements and procedures;

C. Defendants shall select and retain, at their expense, an independent person

or persons (the "CGMP expert"), who has no personal or financial ties (other than the retention agreement), to Defendants and their families, and who by reason of background, training, education, or experience, is qualified to inspect Defendants' drug and device manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP and 21 U.S.C. § 351(h), 21 C.F.R. Parts 806 and 820, 21 U.S.C. § 352(t)(2), 21 C.F.R. Part 803, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-11, and this Decree. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as it retains such expert; and

D. Defendants shall submit a protocol that identifies the work plan (the "work plan") for the CGMP expert and the methodology that will be used by the CGMP expert to ensure that Defendants' corrective actions are implemented and that the manufacturing, processing, packing, labeling, holding, and distribution of drugs and devices is operated and will be continuously administered in conformity with CGMP for both drugs and devices. In addition to assuring general conformance with CGMP, the work plan must address, to FDA's satisfaction, the requirements in paragraph 19(A)(1) - (13) and 19(B)(1) - (10). Defendants shall first obtain FDA's written approval of the work plan prior to the CGMP expert performing his or her inspection as set forth in paragraph 19(E)-(F); and

E. The CGMP expert shall perform a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs and devices. The CGMP expert shall determine whether Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs and devices are in compliance with CGMP for both drugs and devices, the Act and its implementing regulations, and this Decree. The CGMP expert shall evaluate whether

Defendants have established a comprehensive written QA/QC program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The CGMP expert shall determine, among other things, whether the QA and QC programs:

(1) Satisfy all requirements in paragraph 19(A) and (B);

(2) Include written standard operating procedures ("SOPs") specifying the responsibilities and procedures applicable to QA or QC personnel and that establish mechanisms to ensure such SOPs are followed; and

(3) Establish mechanisms to ensure that written SOPs are periodically re-evaluated so that they remain in continuous compliance with CGMP for drugs and devices, and that the SOPs address all facets of CGMP and are reviewed and controlled by an independent QA unit; and

F. The CGMP expert's certification shall include a full and complete written report with the detailed results of the CGMP expert's inspections and evaluation. The CGMP expert's certification report shall include, but not be limited to, the following:

(1) He or she has inspected Defendants' facilities, methods, processes, and controls for drug and device manufacturing;

(2) Defendants have satisfied all requirements in paragraphs 19(A), (B) and (D);

(3) All CGMP deviations brought to Defendants' attention since July 17, 2009 either by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected;

(4) Steps taken by Defendants to comply with 21 U.S.C. §§ 351(h) and 352(t)(2), and 21 C.F.R. Parts 806 and 820 and CGMP;

(5) Steps taken by Defendants to comply with 21 U.S.C. § 351(a)(2)(B) and 21

C.F.R. Parts 210-11 and CGMP;

(6) Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP for both drugs and devices; and

(7) As part of this certification, the CGMP expert shall include a complete and detailed report of the results of his or her inspection that includes all findings of violations of CGMP;

G. Defendants submit to FDA for approval a written batch certification protocol ("certification protocol") for drugs, and shall not commence batch certification until FDA has first approved the certification protocol in writing. Upon FDA's written approval of the certification protocol, and FDA's communication to Defendants in accordance with paragraph 19(J), Defendants' CGMP expert shall: (1) witness the manufacture of three (3) batches from each of the drug product line families manufactured by defendants set forth in the approved certification protocol (*e.g.*, nasals, cough and colds, hemmorrhoidal wipes and pads, glycerin suppositories), including one batch from the drug product in each product line family that represents the "worst case" product for that product line family; (2) examine the manufacturing and control records, and the raw data associated with such records for each drug; and (3) certify in writing that the products meet the requirements of the certification protocol; and

H. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants attention since July 17, 2009, by FDA, the CGMP expert, and any other source including, but not limited to, any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs and

devices are operated and will be continuously administered in conformity with CGMP and the Act, 21 U.S.C. § 351(h), 21 C.F.R. Parts 806 and 820, 21 U.S.C. § 352(t)(2), 21 C.F.R. Part 803, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-11, and this Decree;

I. Within thirty (30) calendar days of receipt of Defendants' report(s) under paragraph 19(H), FDA may, in its discretion and without prior notice, commence an inspection of Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, its implementing regulations, and this Decree; and

J. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 19(A)-(H). In no circumstance may FDA's silence be construed as a substitute for written notification. If the Defendants indicate to FDA in writing that they do not seek approval to resume the manufacture, processing, packing, labeling, holding, or distributing of devices, then the requirements of paragraph 19(A)-(H) that apply to devices may be pursued by Defendants at such future time when Defendants intend to resume their device manufacturing, processing, packing, labeling, holding, or distribution, and any FDA notice issued pursuant to this subparagraph J will clarify its applicability to drugs or devices or both, as appropriate.

20. Nothing in paragraph 19 of this Decree shall preclude the Defendants from receiving, holding, and distributing in the United States any finished drug products that are in compliance with the Act that Defendants purchase from a third party or parties, so long as:

A. Defendants do not manufacture, process, pack, or label such finished drug products and act only as a distributor of such products;

B. The third party or parties who manufacture or supply the finished drug

products to Defendants are not owned or controlled by or affiliated in any way with, Defendants, and have no connection to Defendants, Defendants' families, or any of Defendants' officers, directors, agents, representatives, employees, successors, assigns, or attorneys;

C. Prior to the Defendants' receipt of finished drug products from any third parties, Defendants' CGMP expert certifies in writing that Defendants have processes in place to ensure that periodic audits of the third parties are performed, third party facilities are adequately monitored, and the third parties are qualified to manufacture and supply the finished products; and the third parties have not been informed by FDA that they have violated the Act;

D. Prior to the Defendants' receipt of finished drug products from any third parties, Defendants CGMP expert certifies in writing that the facilities used by Defendants to receive, hold, and distribute finished drug products have adequate controls for temperature, humidity, and light and such other control systems as are necessary to prevent contamination, mix ups, or other violations of CGMP; and

E. If any significant violations of CGMP are found during an inspection of any third party provider of finished drug products or through Defendants' own monitoring of third parties, then FDA may, at its discretion, invoke any of the actions set forth in paragraph 23.

21. After Defendants receive written communication from FDA pursuant to paragraph 19(J), Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of Defendants' drug and device manufacturing operations no less frequently than once every six (6) months for a period of three (3) years, and annually thereafter for an additional two (2) year period. If Defendants receive separate paragraph 19(J) communications from FDA (*i.e.*, a written communication with respect to drugs and a subsequent communication with respect to devices), then each such communication will initiate

a separate five (5) year audit period. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) with any of Defendants' officers or employees or their immediate families and may, if Defendants choose, be the same person or persons described as the CGMP expert, as set forth in paragraph 19; and

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP, the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection(s) is completed. If any audit report identifies deviations from the Act, its implementing regulations, or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain the audit reports in separate files at its facilities and shall promptly make the audit reports available to FDA upon request;

B. If an audit report contains any adverse observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) calendar days, Defendants shall, within fifteen (15) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections

("correction schedule") and provide justification describing why the additional time is necessary. Before becoming effective, the correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations, and within five (5) business days of beginning that review, the auditor shall simultaneously report in writing to FDA and Defendants his review and conclusions whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected; and

C. In addition to the foregoing audit reports, Defendants' auditor shall, with respect to each drug and/or device that has been approved by FDA for distribution following the successful completion of batch certification described in paragraph 19(G) and resumption of manufacture and distribution under paragraph 19(J), report in writing to FDA on a quarterly basis, beginning with the date of entry of this Decree, whether the succeeding batches of such product(s) meet the protocol certification requirements.

22. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to Defendants' facilities including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; to take photographs

and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drugs and devices, including components thereof, in order to ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

23. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions, which Defendants shall immediately implement, including, but not limited to, the following:

A. Cease all manufacturing, processing, packing, repacking, labeling, holding, and/or distributing any or all drug(s) and/or device(s);

B. Recall, at Defendants' expense, any drug and/or device manufactured, processed, packaged, labeled, held, or distributed by Defendants that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a safety alert with respect to a drug and/or device manufactured, processed, packaged, labeled, held, or distributed by Defendants; and/or

F. Take any other corrective actions as FDA in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

24. Any cessation of operations or other action described in paragraph 23 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA shall determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting resumption of operations. The costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraphs 23, shall be borne by Defendants at the rates specified in paragraph 26 of this Decree.

25. The parties may at any time petition each other in writing to extend any deadline provided for herein; and, if the parties mutually agree to extend a deadline, such extension may be granted without seeking leave of Court.

26. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per

representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

27. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

28. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

29. Defendants shall notify FDA, in writing at least fifteen (15) days before any change in ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the structure or identity of Defendants (or any of any of Defendants' parents or subsidiaries), or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree.

Defendants shall provide a copy of this Decree to any prospective successor or assignee at least thirty (30) days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than thirty (30) business days prior to such assignment or change in ownership.

30. Within ten (10) business days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service, personal delivery via electronic mail with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested), to each and all of the following "Associated Persons": employees, directors, officers, agents, representatives, attorneys, successors, and assigns of Defendants, and any and all persons or entities in active concert or participation with any of them, including, but not limited to, all others involved in the manufacture of Defendants' products. In the event that any Defendant becomes associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall within fifteen (15) calendar days of such association provide a copy of this Decree to such person(s) by electronic mail with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested). Within twenty (20) calendar days of the date of entry of this Decree, Defendants shall hold a general meeting or a series of smaller meetings for all persons with responsibility for operations and manufacturing at any facility where Defendants manufacture, process, pack, or hold articles of drug and/or device for introduction into interstate commerce, and upon the opening of any new such facility, at which it shall describe the terms and obligations of this Decree. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall furnish FDA with an affidavit of compliance with this paragraph (signed by a person with personal knowledge of the facts). Such affidavit should identify the names, addresses, and positions of all new Associated Persons that received a

copy of the Decree.

31. Defendants shall post a copy of this Decree in the employee common areas at facilities where Defendants manufacture, process, pack, store, or distribute articles of drug and/or device for introduction into interstate commerce, within ten (10) calendar days of the entry of this Decree or, if any new such facility is opened, within ten (10) calendar days of opening, and shall ensure that the Decree remains posted for a period of at least one year. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit (signed by a person with personal knowledge of the facts) stating the fact and manner of its compliance with this paragraph.

32. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to: District Director, FDA Minneapolis District Office, 250 Marquette Avenue, Suite 600, Minneapolis, MN, 55401.

33. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages per violation per day of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of an adulterated drug and/or device, in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil

penalties or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

34. This Decree does not in any way limit any administrative, civil, or criminal action that may be deemed appropriate to be taken by any agency or department of the United States.

35. This Court retains jurisdiction to issue such further Decrees and orders as may be necessary to the proper disposition of this proceeding.

SO ORDERED, this 13th day of June, 2011.

AARON E. GOODSTEIN
UNITED STATES MAGISTRATE JUDGE

Entry consented to:

For Defendants

s/ERIC C. HAERTLE
ERIC C. HAERTLE
Individually and on behalf of
H & P Industries, Inc., as its
President and/or Chief Operating
Officer, Triad Group, Inc. as its
Chief Operating Officer, and
Triad Disposables, Inc., as its
Vice President

s/DAVID R. HAERTLE__
DAVID R. HAERTLE
Individually

s/DONNA L. PETROFF
DONNA L. PETROFF
Individually

s/MAX B. CHESTER____
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